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Simultaneous Tracking of Catheters and Guidewires: Comparison to Standard Fluoroscopic Guidance for Arterial Cannulation

S. Condino [a,*], E.M. Calabrò [a], A. Alberti [b], S. Parrini [a], R. Cioni [c], R.N. Berchiolli [b], M. Gesi [d], V. Ferrari [a], M. Ferrari [a,b]

[a] EndoCAS Center, Department of Translational Research on New Technologies in Medicine and Surgery, University of Pisa, Italy
[b] Unit of Vascular Surgery of the Department of Translational Research on New Technologies in Medicine and Surgery, University of Pisa, Pisa, Italy
[c] Division of Diagnostic and Interventional Radiology, Department of Translational Research on New Technologies in Medicine and Surgery, University of Pisa, Italy
[d] Department of Translational Research on New Technologies in Medicine and Surgery, University of Pisa, Pisa, Italy

WHAT THIS PAPER ADDS

In vitro evaluation of an innovative three-dimensional electromagnetic navigation platform, the principal peculiarity of which is the real-time tracking of both guidewires and catheters to guide endovascular procedures with a reduced X-ray dose and contrast medium injection.

Objectives: The purpose of this in vitro study was to clinically assess the feasibility of a three-dimensional (3D) electromagnetic (EM) navigator, including sensorized catheters and guidewires, to determine any reduction in radiation dose and contrast medium injection.

Methods: The study was performed using a navigator prototype developed at the EndoCAS center. The system includes catheters and guidewires simultaneously tracked with an EM localizer (Aurora, Northern Digital, Waterloo, Canada). Tests were performed on a commercial abdominal aortic aneurysm model. Fifteen operators were asked to cannulate renal arteries using the conventional fluoroscopic guidance and the EM navigator without fluoroscopic support. Each trial was video-recorded and analyzed for timing and success of completing the cannulation task by two blinded and independent observers. Performances were also qualitatively evaluated using the Imperial College Endovascular Cannulation Scoring Tool (IC3ST). Moreover, a questionnaire was administered to participants to evaluate the navigator potentialities.

Results: Quantitative analysis results show no significant difference between the fluoroscopic and EM guidance regarding the total procedure time (median 2.36 minutes [interquartile range {IQR} = 1.26–4.7) vs. 2.95 min [IQR = 1.35–5.38], respectively; $p = .93$); number of total hits with catheter/guidewire tip to vessels wall (median 5.50 [IQR = 2.00–10.00] vs. 3.50 [IQR = 2.50–7.00], respectively; $p = .65$); and number of attempts at cannulation (median 4.0 [IQR = 2.00–5.00] vs. 4.0 [IQR = 2.00–5.00], respectively; $p = .72$). Moreover, there was no significant difference between the IC3ST score obtained using the EM navigator and the traditional method (average 22.37 [STD = 7.95] vs. 21.58 [STD = 6.86]; $p = .92$). Finally, questionnaire results indicate a general agreement concerning the navigator usefulness, which clearly shows the positions of instruments inside the 3D model of the patient's anatomy. Participants also agreed that the navigator can reduce the amount of contrast media delivered to the patient, as well as fluoroscopy time.

Conclusions: This work provides proof of concept that simultaneous EM navigation of guidewires and catheters is feasible without the use of live fluoroscopic images.

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INTRODUCTION

Traditional fluoroscopy-guided endovascular procedures have several limitations, including exposure of the patient and clinical staff to ionizing radiation and the use of nephrotoxic contrast medium. Moreover, convectional C-arms provide only bi-dimensional images and the consequent lack of depth perception makes it difficult for the surgeon to estimate the spatial relationships between the endovascular instruments (e.g., catheters and guidewires) and the patient's anatomy. As a result, in cases of difficult angulations and tortuous anatomies, even a conceptually simple task, such as vessel cannulation, can become challenging and time-consuming, thus requiring prolonged fluoroscopic exposure time and the injection of large volumes of contrast medium.

In an attempt to overcome some of the aforementioned limitations and reduce the perceptual difficulties due to the

* Corresponding author. S. Condino, EndoCAS Center, Università di Pisa, Ospedale di Cisanello, Via Paradisa 2, 56124 Pisa, Italy.
E-mail address: sara.condino@endocas.org (S. Condino).

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lack of depth perception, multimodal imaging strategies have been developed. For example, live fluoroscopic images containing the real-time information on interventional devices position can be registered with a three-dimensional (3D) model of the patient anatomy, acquired intraoperatively (with a 3D rotational angiography [3DRA] or an X-ray/magnetic resonance (XMR) system) or from a previous scan.[1–4] The resulting fused images provide detailed 3D information regarding the vascular morphology and pathology; moreover, the amount of contrast agent can be potentially reduced, as vascular structures can be visualized thanks to the initial 3D model, without injecting additional contrast medium. Despite these advantages, during the procedure surgeons still have to rely on fluoroscopic images to guide the instruments.

Recent studies have attempted to reduce also the intraprocedural radiation exposure by monitoring the instruments position without an X-ray imaging system. For example, methods have been studied to track catheters and guidewires in the MR environment;[5] but, besides the technical difficulties related to the instrument tracking, these MR-guided techniques are limited by the lack of a MR-compatible instrumentation with proper mechanical characteristics.

Finally, new techniques have been developed to partially replace fluoroscopic guidance with systems based on the integration of preoperative radiological images and electromagnetic (EM) tracking technology. For example, in 2004, Pujol et al.[6] developed a navigator based on the registration of preoperative computed tomography (CT) images, two-dimensional US data, and the EM tracking of a modified catheter. In another major study, Sidhu et al.[7] evaluated the feasibility of an EM-based approach to arterial cannulation using the StealthStation Guidance System (Medtronic, Louisville, CO, USA) to display the position of the tip of a sensorized guidewire within a 3D model of the vascular anatomy. This latter study confirmed previous findings and contributed additional evidence suggesting how the EM technology might offer potential benefits in the execution of surgical tasks and reducing the fluoroscopic dose. Despite these promising results, all the existing systems manage to track either the guidewire distal part or the catheter tip; thus, they still rely on fluoroscopy.

Results obtained by Cochennec et al.,[8] for example, suggest that relying solely on the StealthStation Guidance System to track the guidewire, the performance of operator is lower than with the traditional fluoroscopic guidance. The simultaneous tracking of both the guidewire and the catheter is, in fact, paramount for an optimal and safe execution of endovascular tasks and thus to achieve better outcomes.

For this reason, we developed, in 2012, an EM system that allows the operator to track, in real time, the guidewire and the catheter, and to reconstruct the distal curvature of the latter.[9] The system was evaluated in vitro during 70 targeting trials and obtained an overall accuracy of 1.2 ± 0.3 mm. The aim of this study is to further prove the in vitro efficacy of the developed navigator by comparing EM navigation with standard fluoroscopy for arterial cannulation, a typical endovascular task.

MATERIALS AND METHODS

EM navigator prototype

The navigator prototype includes sensorized catheters and guidewires simultaneously tracked with the NDI Aurora (Northern Digital, Waterloo, Canada) EM localizer and allows the operator to follow their movements inside a 3D map of the patient's anatomy extracted from 3D radiological images (e.g., preoperative CT or intraoperative 3DRA).

In particular, two NDI Aurora sensor coils (5 degrees of freedom [DOF], 0.5 mm diameter $\times$ 8 mm length) are used to track 5-F cobra-shaped catheters (Fig. 1), while a single coil (5 DOF, 0.3 mm diameter $\times$ 12 mm length) is employed to sensorize ad hoc-made 0.035-inch guidewires (Fig. 2).

Thanks to a calibration procedure detailed in a previous publication,[9] the two sensors embedded in the catheter enable the calculation of the catheter tip position, orientation of the tip axis (A1), and, finally, orientation of the catheter axis (A2) in correspondence to the second sensor. Moreover, from A1 and A2, it is possible to infer the deformation of the catheter distal part (the tract between the two sensors).

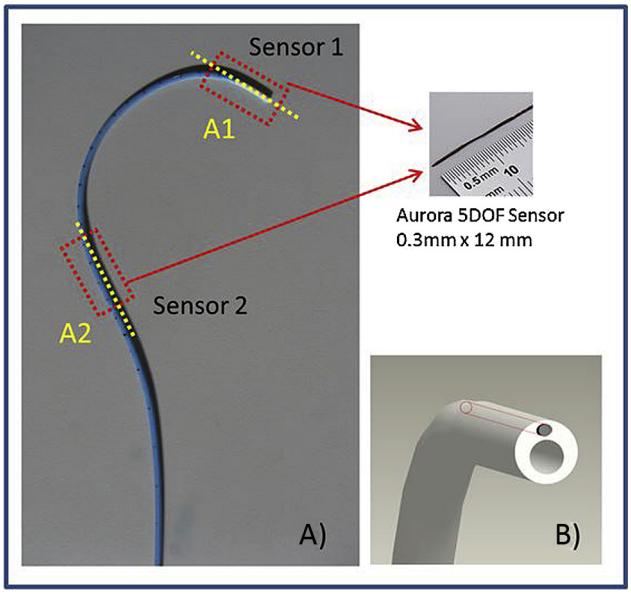

Figure 1. A sensorized 5-F cobra catheter. The catheter is made modifying a steerable angiographic catheter, the Orienter from Angiologica (S. Martino Siccomario, Pavia, Italy). The Orienter has two lumens: one operative and the other for the steering cable. For our particular application, the catheter distal portion is thermoformed to have a cobra-shaped tip, the steering cable is removed and two Aurora sensors are inserted within its lumen (A). Sensors positions are highlighted in red: the axes of the coils are aligned with that of the catheter operative lumen. More particularly, one sensor is positioned at the catheter tip (B), while the other, which provides the sixth degree of freedom, is positioned few centimeters below the first coil to acquire information about the curvature of the catheter distal part.

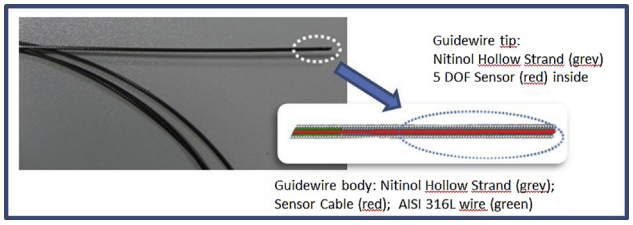

Figure 2. Ad hoc-made sensorized guidewire (0.035-inch). A NDI Aurora coil is inserted inside a nitinol helical hollow strand (suitable for endovascular application) from Fort Wayne Metals (Fort Wayne, IN, USA) 0.035 inches in diameter and 180 cm long, strengthened with an AISI 316L inner wire. The dotted line indicates the sensor position. The guidewire inner structure is shown. Notice that the steel core does not extend to the guidewire tip, which is more flexible.

This innovative sensorization strategy represents a necessary step to avoid the need for live fluoroscopic images. Indeed, to correctly perform an endovascular procedure, the surgeon needs to know simultaneously the position of the guidewire and the catheter, and to check the distal curvature of the latter (especially after the withdrawal of the guidewire from the catheter head).[10] Fig. 3 highlights the limit of a navigator able to track only the guidewire tip: the lack of visual information on the catheter position may lead to dangerous collisions of the instruments with the vessels and it does not allow the surgeon to perform complex endovascular tasks (if not opportunely combined with fluoroscopy).

A semi-automatic tool, the EndoCAS Segmentation Pipeline[11,12] integrated in the software ITK-SNAP (www.itksnap.org), is used to process 3D radiological images (CT, magnetic resonance imaging, or 3DRA series) in order to extract the 3D model of the patient's anatomy.

A registration procedure is needed to coherently merge the radiological information content (the 3D geometrical description of the anatomy) and EM data (instruments position and orientation). Registration problems/errors can be partially solved using an intra-operative imaging source, such as a 3D C-ARM, to acquire the 3D model of the anatomy just before the intervention. This ensures a precise correspondence between the radiological data set and the patient's anatomy, at least for the arteries which are not deformed by breathing (other arterial movements could, instead, be predicted by monitoring the breathing signal[13–15]). A simple method to find the rigid static transformation between the 3D C-arm and the EM localizer reference frames is based on the use of a calibration phantom and a point-based calibration with a least-squares error minimization algorithm.[9]

Once the registration/calibration matrix is calculated, the system can display the position of the guidewire and the

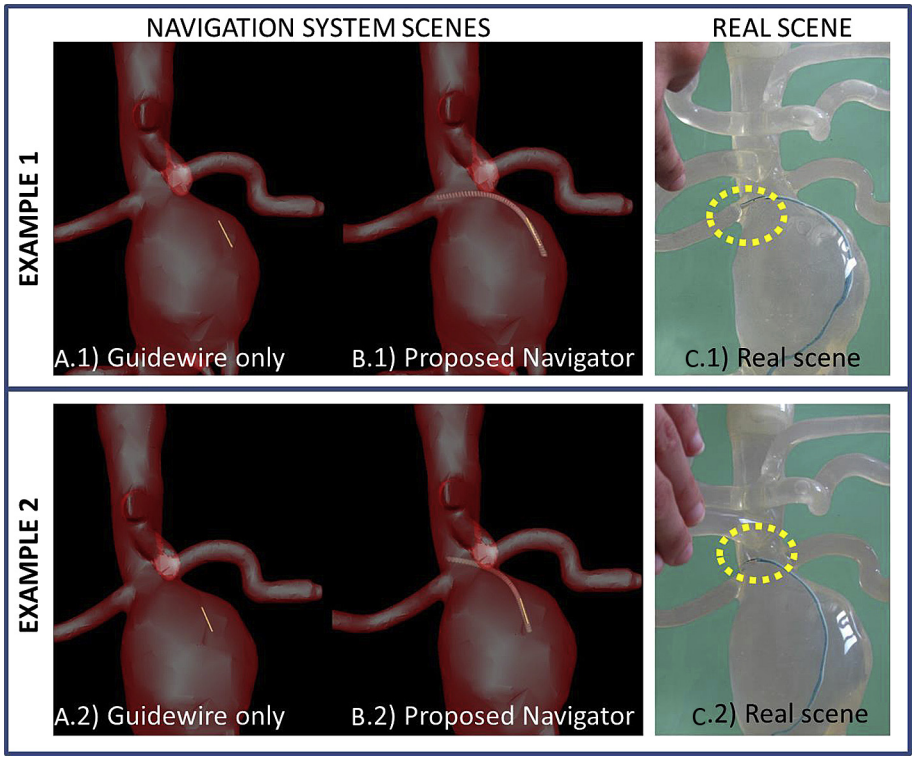

Figure 3. Two exemplary situations which highlight the importance of tracking both the catheter and the guidewire. In example 1 and example 2 the position of the guidewire is almost the same, while the position of the catheter is different. A navigator which shows only the position of the guidewire (A.1, A.2) could not allow the surgeon to distinguish between these two different situations. Such a lack of visual information can be only partially compensated by the force feedback and it is dangerous for the potential collisions of the instruments with the vessel walls. Instead, our navigator clearly shows the position of both the instruments, thus the surgeon can easily cannulate the target ostium avoiding fluoroscopy.

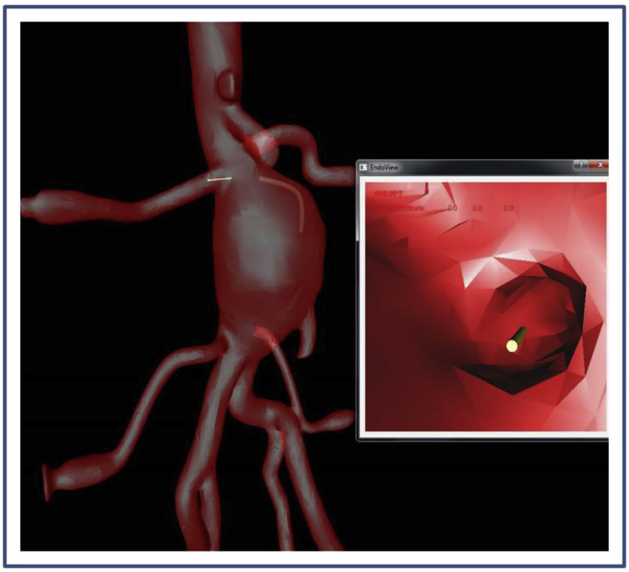

Figure 4. Example of virtual scene showed by the navigator. The endoscopic view is rendered from a virtual camera positioned at the catheter tip.

catheter inside the 3D model of the vasculature, allowing the surgeon to perceive the spatial relationship between these instruments and the patient's anatomy. Moreover, the surgeon can select a "virtual endoscopic view" aligned with the catheter tip (Fig. 4).

Testing environment

In vitro tests were performed on an abdominal aortic aneurysm model connected to a continuous pump for circulation of water (Elastrat Sàrl, Geneva, Switzerland) (Fig. 5). This simulator is transparent and thus suitable for use with video monitoring. It is also compatible with imaging modalities, such as digital subtraction angiography and CT.

EM-guided trials were performed in a setup comprising the navigator and the simulator (Fig. 6). Fluoroscopy was performed with a GE Innova fluoroscopy unit (GE

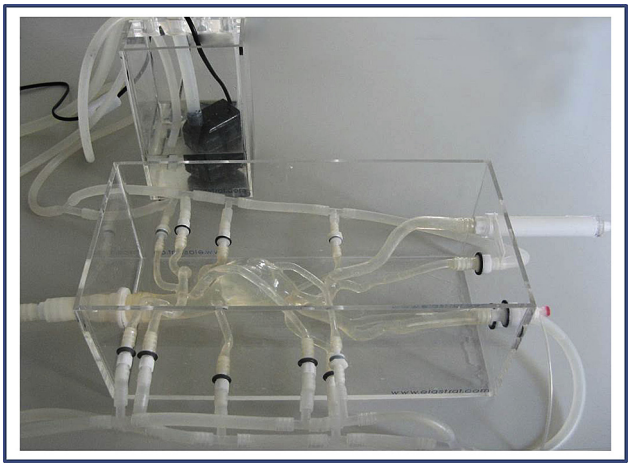

Figure 5. Abdominal aorta aneurysm model used for the in vitro test.

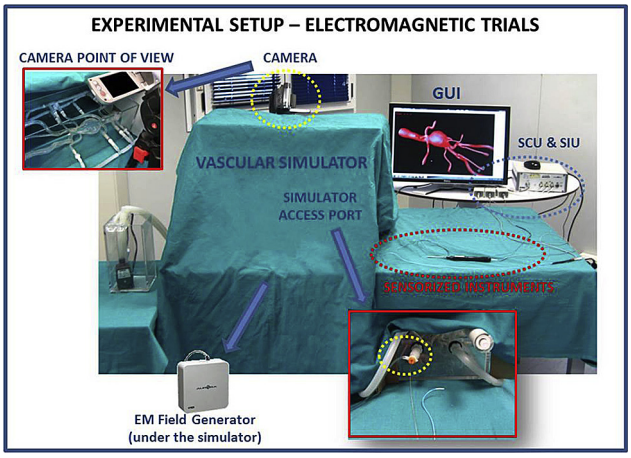

Figure 6. Experimental setup of the electromagnetic (EM) trials. The picture shows the graphical user interface (GUI), the system control unit (SCU), and the sensor interface units (SIU), while the EM field generator is placed under the vascular model.

Healthcare, Waukesha, WI, USA) (Fig. 7). A video camera was mounted on a tripod to provide a close-up view of the aneurysm model and to record endovascular instruments movements within the phantom. The vascular model was covered with a surgical drape to make the operator look only at the graphical user interface (GUI), during EM trials, and at the fluoroscopic images on the monitor during fluoroscopically-guided trials.

Participants

Fifteen participants, including vascular surgeons and interventional radiologists, were recruited for this study. For analytical purposes, participants were divided into two groups on the basis of their experience in endovascular procedures. The "expert group" consisted of five participants who had performed at least 100 endovascular procedures as primary operator, whereas the "low experience" group included 10 operators who had performed 20 or fewer procedures. The designation of the latter group was based on the definition of novice endovascular interventionalists in previous studies.[16] Ethical approval was not

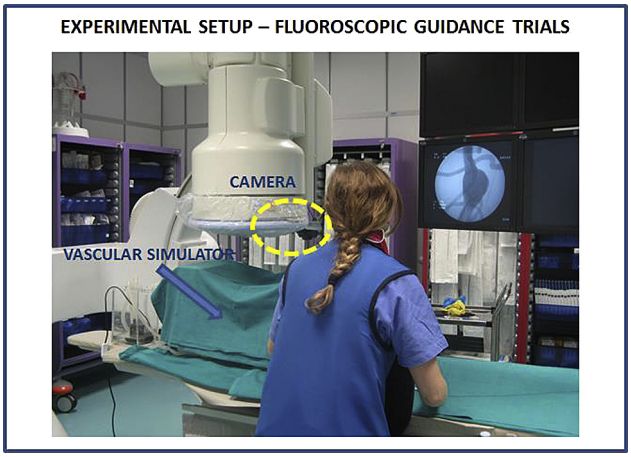

Figure 7. Experimental setup of fluoroscopic guidance trials.

necessary for the study; however, all participants gave informed written consent to participate.

Study protocol

CT images of the vascular model were acquired. Three fiducial markers were identified and used for a point-based registration. To assess the potentialities of the EM navigator, all participants were asked to cannulate simulator renal arteries.

Before starting the study, all participants received the same standardized teaching session on the navigator functionalities and components, followed by a 1-minute training session to try the sensorized instruments inside the phantom. During this practical session participants were not allowed to cannulate vessels; moreover, they were not allowed to see the vascular model until the study was completed (the model was covered with a surgical drape). After the training, operators were informed of the assessed task and the scoring criteria.

Participants were randomized to fluoroscopically- or EM-guided cannulation first. During the test, passive support was provided by an assistant (to interact with the navigator GUI) or a radiology technician, but hands-on assistance was not permitted. All the trials with the navigator were completely executed without fluoroscopic support. The available endovascular instruments were the same for all participants and for all the trials (fluoroscopically- or EM-guided).

The available time to cannulate each artery was 20 minutes; the trial was considered successfully completed when the operator was able to cannulate both the renal arteries inserting the catheter more than 3 cm into the vessel within the given time.

At the end of the study, all participants were asked to complete an anonymous questionnaire to evaluate the navigator functionalities.

All the sessions were video-recorded and evaluated according to the protocol described in the next section.

Performance evaluation and questionnaire

Each trial was assessed by two independent and blinded observers, and analyzed for both timing and success of completing the cannulation task.

The performance of operators who successfully completed the task with both the approaches (fluoroscopic and EM guidance) was quantitatively assessed by measuring total procedure time (measured from when the catheter entered the aorta to its insertion into the target vessel); total fluoroscopy time; number of attempts at cannulation; and total hits with catheter/guidewire tip to vessels wall.

The Imperial College Endovascular Cannulation Scoring Tool (IC3ST), a validated scoring system used for endovascular skills assessment,[7,17,18] was used to qualitatively evaluate the performance of all participants. The IC3ST comprises eight criteria, and the scoring scale in each domain ranges from 1 (poor performance) to 5 (excellent performance). In this study the surgical equipment was standardized and the first domain ("catheter use": to assess participants' ability to choose an appropriate catheter and recognize catheter unsuitability) was not used.

Finally, we administered to participants a questionnaire (see Table 3) comprising 14 items assessed using a five-point Likert scale grouped under three headings: evaluation of the hardware components, evaluation of navigator software, and general evaluation. This latter group aims to assess the potential advantages of the EM navigator with respect to fluoroscopy.

Statistical analysis

Statistical analysis was performed using the SPSS Statistics Base 19 software.

McNemar's test was used to examine differences between the two guidance modalities in terms of successful completion of task, and a p-value $<.05$ was considered to denote statistical significance.

Results of the quantitative assessment are expressed as median values with the interquartile range (IQR) of the measurements taken by the two independent observers, while qualitative results are presented as the average value and standard deviation of the IC3ST scores. Difference in cannulation performance between using the fluoroscopic method and the EM navigator were compared using the Wilcoxon signed-ranks test. A p-value $<.05$ was considered to denote statistical significance.

The central tendencies of responses to a single Likert item are summarized by using median, with dispersion measured by IQR. The Wilcoxon signed-ranks test was used to determine the significance of the responses to each item evaluating if the operators were significantly more likely to agree or disagree with each of the statements. A p-value $<.05$ was considered statistically significant.

RESULTS

All the experts successfully cannulated the renal arteries with both EM and fluoroscopic guidance, while only six participants in the "low experience group" completed the task with both the approaches. In particular, these operators failed to cannulate the left renal artery: one operator failed with the fluoroscopic guidance, but completed the task with the EM navigator; two participants failed with the navigator, but completed the task with the fluoroscopic guidance; one operator failed with both the approaches. The McNemar's test revealed (two-tailed p-value based on the binomial distribution $= 1.00$) that the guidance modality had no statistically significant influence on the successful completion of the task.

Quantitative analysis results (Table 1) indicate no statistically significant differences between fluoroscopic and EM guidance, regardless of the operator's level of experience. In fact, for both groups no significant differences in terms of total procedure time, number of total hits with catheter/guidewire tip to vessels wall, or number of attempts at cannulation were found.

Table 1. Quantitative assessment results: comparison between using the electromagnetic (EM) navigator and the traditional method for low experienced and expert operators. Results are expressed as median values with interquartile range (IQR) (25°; 75°).

		Total time (min)	Fluoroscopy time (min)	Total vessel wall hits	Attempts at cannulation
Low experienced group	Fluoroscopic guidance median (IQR)	3.17 (1.80; 8.19)	2.60 (2.03; 1.20)	8.00 (1.88; 11.26)	4.00 (3.50; 6.50)
	EM navigator median (IQR)	4.56 (2.37; 7.66)	0	6.25 (2.88; 8.88)	4.5 (3.75; 6.75)
	p	0.92	—	0.75	0.53
Expert group	Fluoroscopic guidance median (IQR)	1.29 (1.07; 7.87)	1.40 (1.20; 2.55)	2.00 (1.75; 13.25)	2.50 (2.00; 6.25)
	EM navigator median (IQR)	1.35 (1.25; 3.99)	0	3.00 (1.25; 4.25)	2.00 (2.00; 4.00)
	p	0.69	—	0.72	0.72
Overall	Fluoroscopic guidance median (IQR)	2.36 (1.26; 4.7)	2.10 (1.30; 3.90)	5.50 (2.00; 10.00)	4.0 (2.00; 5.00)
	EM navigator median (IQR)	2.95 (1.35; 5.38)	0	3.50 (2.50; 7.00)	4.0 (2.00; 5.00)
	p	0.93	—	0.65	0.72

A similar result is obtained when operators performance was qualitatively assessed with the IC3ST scoring tool. Indeed, Table 2 shows no statistical difference between the total score obtained by the two groups using the EM navigator and the traditional method.

Finally, as for the result of the questionnaire Table 3 shows that there is overall significant agreement with the following statements: “the GUI is user friendly”; “the GUI clearly shows instruments positions inside the anatomy 3D model”; “the simulated endoscopic view is useful”; “the navigator 3D scene is reliable and consistent with the reality”; “the navigator can reduce exposure of the patient and the clinical staff and the administration of contrast medium”. On the contrary, a significant disagreement was expressed with the statements regarding the catheter torquability and pushability: they were considered not suitable for endovascular procedures.

DISCUSSION

In this study a cannulation task was chosen to evaluate an innovative 3D EM navigation platform and to compare the EM system with conventional fluoroscopic guidance. Renal arteries were chosen as targets of the cannulation trial. All the experts successfully performed the task, but only 3/5 of the low-experienced participants were able to cannulate both arteries. This underlines the realism of the testing setup of and the difficulty of the task, which requires advanced psychomotor and perceptual skills, and can be considered a reliable starting point to test the navigator functionalities.

Although obtained results should be confirmed in different vascular territories, this work provides proof-of-concept of the efficacy of the navigator to guide endovascular procedures; indeed, both quantitative and qualitative data show no significant differences between using the traditional fluoroscopic method and the EM navigator.

Moreover, as preliminarily showed by the obtained results, the proposed navigator could allow avoidance of the need for real-time fluoroscopy and angiography, thus reducing X-ray exposure (of the patient and clinical staff) and the contrast medium administered. This is proven, preliminarily, by the quantitative data analysis and by the questionnaire results.

Furthermore, a general agreement was obtained concerning the usefulness and reliability of the navigator scene, which is user-friendly and clearly shows the position of the instruments inside the 3D model of the patient’s anatomy. Positive feedback was also obtained on the role and the usefulness of the endoscopic view.

Finally, questionnaire results highlight the need for improvements in the instruments constructive characteristic and, in particular, the catheters torquability and pushability. In the future, other selective catheters will be sensorized and the navigator hardware components will be optimized in order to improve the reliability and safeness of the system before its clinical application.

At this time, the proposed navigator cannot compensate for breathing and cardiac cycle movements as it is based on a static representation of the anatomy; therefore, it can be used for arteries with a steady origin and preferably with a steady course. Future research will attempt to compensate such movements, updating the model of the anatomy on the basis of predictive respiratory motion model,[15,19] and/or intraoperative data, such as 3D ultrasound.[20]

Table 2. Qualitative assessment results: comparison between the Imperial College Endovascular Cannulation Scoring Tool scores obtained by low experienced and expert operators using the electromagnetic (EM) Navigator and the traditional method. Average scores and standard deviations are reported.

	Fluoroscopic guidance (average value [STD])	EM navigator (average value [STD])	*p*
Low experienced group	20.6 (7.39)	19.3 (8.06)	.36
Expert group	28.5 (2.12)	23.4 (5.96)	.23
Overall	21.58 (6.86)	22.37 (7.95)	.92

Table 3. Questionnaire results. The central tendency of responses is summarized by using median with dispersion measured by Interquartile range (IQR) (25°; 75°). Statistically significant *p*-values (<.05) are highlighted.

		Low experienced group		Expert group		Overall	
		Median (IQR)	*p*	Median (IQR)	*p*	Median (IQR)	*p*
Hardware	The torquability of the catheter is suitable for endovascular procedures	1.5 (1.0; 2.3)	.01	1.5 (1.0; 2.3)	.04	2.0 (1.0; 2.0)	.01
	The pushability of the catheter is suitable for endovascular procedures	2.5 (1.8; 3.0)	.04	2.5 (1.8; 3.0)	.10	2.0 (2.0; 3.0)	.01
	The overall characteristics of the catheter are suitable for endovascular procedures	3.0 (2.5; 3.25)	.46	3.0 (1.0; 3.3)	.28	3.0 (1.0; 3.0)	.08
	The pushability of the guidewire is good	3.0 (2.0; 4.0)	.79	3.5 (1.8; 4.3)	.78	3.0 (2.0; 4.0)	.51
	The overall characteristics of the guidewire are suitable for endovascular procedures	3.5 (2.8; 4.0)	.43	4.0 (2.5; 4.3)	.40	3.0 (2.0; 4.0)	.90
Software	The GUI is user friendly	4.0 (4.0; 5.0)	.01	4.5 (4.0; 5.0)	.02	4.0 (4.0; 5.0)	.01
	The GUI clearly shows instruments positions inside the anatomy 3D model	4.5 (3.8; 5.0)	.02	4.5 (3.8; 5.0)	.04	4.0 (4.0; 5.0)	.01
	The simulated endoscopic view is useful	4.0 (2.8; 5.0)	.06	4.0 (3.5; 5.0)	.09	4.0 (3.0; 5.0)	.01
	The navigator 3D scene is reliable and consistent with the reality	4.0 (3.0; 4.3)	.02	4.0 (3.0; 5.0)	.06	4.0 (3.0; 4.0)	.01
General evaluation	It was easier to cannulate the vessels with the navigator than with the fluoroscopic guidance	2.0 (1.8; 3.3)	.11	2.0 (1.0; 2.5)	.08	3.0 (2.0; 4.0)	.49
	The navigator can simplify endovascular procedures	4.0 (2.8; 4.3)	.11	4.0 (3.5; 5.0)	.08	4.0 (3.0; 4.0)	.07
	The navigator can reduce the time to cannulate vessels	3.5 (2.0; 4.3)	.27	4.0 (2.0; 5.0)	.23	4.0 (2.0; 4.0)	.18
	The navigator can reduce exposure of the patient and the clinical staff and contrast administration	3.5 (2.0; 4.3)	.01	5.0 (5.0; 5.0)	.01	5.0 (5.0; 5.0)	.01
	The navigator can reduce complication rates	5.0 (5.0; 5.0)	.13	4.0 (2.8; 4.3)	.16	3.0 (3.0; 4.0)	.12

Note. GUI = graphical user interface; 3D = three-dimensional.

The cost of the system is expected to be comparable to other EM navigational devices. Research addressing the cost-effectiveness of the navigator is needed for a complete comparison of EM-guided procedures with standard fluoroscopically-guided interventions.

In conclusion, this work provides proof-of = concept for the use of the EM navigation in guiding catheters and guidewires without the need for live fluoroscopic images. In the future, further animal and clinical experiments will be performed for a complete surgical validation.

CONFLICT OF INTEREST

None.

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